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Agricultural Situation

Japan's proposed revision of Food Sanitation Law 2002

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Report Highlights: The Ministry of Health, Labor, and Welfare (MHLW) released the texts of its proposed draft legislation, revising of Japan's Food Sanitation Law. MHLW is soliciting comments on the legislation until December 10, 2002.

Includes PSD changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1], JA

In keeping with previous advance announcements of legislative text, Japan's Ministry of Health, Labor and Welfare (MHLW) released the texts of its proposed draft legislation, revising of Japan's Food Sanitation Law. The tentative translation of this text is available in this report. MHLW will accept public comments on the proposed text until December 10, 2002. In a meeting held on November 13, 2002, MHLW explained that it would notify the World Trade Organization's Committee on the Application of Sanitary and Phytosanitary Measures in December, 2002.

The text will be proposed in the upcoming Diet (house of representatives) session, which begins in January 2003. Given widespread concerns over food safety, the enactment of the revised Food Sanitation Law is forecast to be completed before the end of the Japanese fiscal year 2003 (31 March 2004).

BEGIN MHLW TENTATIVE TRANSLATION

Framework Draft with Regard to the Review of Food Sanitation Regulations
(Framework draft concerning the revision of the Food Sanitation Law and related laws and regulations)

I. Purpose

The government has been preparing for the establishment of the Food Safety Committee (tentative name) that will evaluate risks of the safety of food and the enactment of the Basic Food Safety Law (tentative name) that will ensure a comprehensive approach to the safety of food, focusing on consumer protection. This preparation has been promoted against the background of the problems related to BSE (bovine spongiform encephalopathy) and false labeling cases that have raised public concern and distrust concerning the safety of food. Studies conducted at the meeting held by ministers in relation to food safety administration provide an additional basis for this preparation.

The government is scheduled to revise the Food Sanitation Law, at the next ordinary session of the Diet, with the aim of protecting the health of the people through the implementation of well-prepared measures to ensure the safety of food. Food sanitation regulations based on the Food Sanitation Law under the jurisdiction of the Ministry of Health, Labour and Welfare are the mainstay of risk management among measures employed by the government for food safety administration.

II. Basic concept

(1) To secure the safety of foods for the protection of the health of the people, the responsibilities of the government, local public entities (including risk communications), and businesses will be clarified. At the same time, a review will be conducted of food sanitation specifications and standards, systems for food sanitation monitoring and inspection, measures against food-derived accidents, such as food poisoning, and penalty.

(2) In the above review, the following will be focused on in consideration of the diversification of the modes of distribution, changes in consumer awareness, and other factors.

- (a) More positive measures to protect the health of the people

New regulations will be introduced and systems will be improved to implement more positive measures to prevent the occurrence and expansion of health damage.

- (b) Promotion of self-regulation by businesses

Businesses that provide food to the public will be urged to implement independent measures in order to secure food safety and prevent any harm from occurring.

- (c) Closer linkage with the regulations on agricultural, livestock and fishery products at their production stages

Food sanitation regulations at all stages from production through to consumption will be established through closer linkages between regulations on agricultural, livestock and fishery products at their production stages, including regulations on agricultural chemicals and pharmaceuticals used for animals.

- (3) The Food Sanitation Law will be appropriately dealt with according to the requirements, based on discussions concerning approaches to risk analysis as well as the responsibilities and roles of relevant bodies for the establishment of the Basic Food Safety Law (tentative name).

III. Main contents of the revision

1. Objectives of the law and responsibilities of the government and other entities

- (1) Reviewing the definition of the objectives of the law

(Concept)

The present Food Sanitation Law provides that its objectives shall be to prevent food from causing harm in relation to sanitation and to contribute to the improvement and the enhancement of public health. The protection of the health of the people through securing the safety of foods should be emphasized as the objective.

(Contents of the revision)

It will provide for the protection of the health of the people through the securement of food safety.

(Related to Article 1)

- (2) Responsibilities of the government and local public entities

(Concept)

Detailed contents of the responsibilities of the government and local public entities should be described

in order to clarify their duties for securing food safety.

(Contents of the revision)

(a) Responsibilities of the government and local public entities

It will be provided that the government and local public entities shall be responsible for (i) the dissemination of knowledge concerning food sanitation, (ii) the collection, organization, analysis, and provision of food sanitation information, (iii) the promotion of food sanitation studies, (iv) solicitation of the views of the public so as to reflect them in policies, (v) the improvement of inspection capacities, (vi) training of human resources to improve their quality, and (vii) cooperation between the government and local public entities. (Newly provided)

(b) Responsibilities of the government

In addition to (a) above, it will be provided that the government shall be responsible for improving inspection systems for food imports, ensuring international cooperation, and providing technical assistance to local public entities. (Newly provided)

(3) Responsibilities of the dealers

(Concept)

The responsibilities of the dealers, including the producers, manufacturers, importers, and distributors, should be described to clarify their responsibility for securing food safety as providers of foods to the public.

(Contents of the revision)

It will be provided that dealers shall be responsible for the prevention of harm caused by food through independent food safety securement and cooperation with the government and local public entities in their implementation of the measures. (Newly provided)

2. Specifications and Standards

(1) Introduction of a positive list system for agricultural chemical residues

(Concept)

Japan will introduce a new system for agricultural chemical residues, considering various factors concerning food safety in Japan, such as a recent increase in imported food. The system, the so-called positive list system, is to prohibit the domestic distribution of foods that contain agricultural chemicals (including veterinary drugs and feed additives) without residue standards established under the Food Sanitation Law. A preparatory period will be placed before the introduction of the system.

(Contents of the revision)

It will be provided that foods containing agricultural chemicals without residue standards will be enjoined from domestic distribution. (Related to Article 7)

As an interim measure for the introduction of the positive list system, the Ministry of Health, Labour and Welfare may set provisional standards for agricultural chemicals for which residue standards are not established, taking account of domestic use, Codex standards, and other standards established with a scientific justification for these chemicals. (Related to supplementary provisions)

Japan will build a system in which at the pre-market registration of agricultural chemicals, residue standards for them are established under the Food Sanitation Law. Also, Japan will step up the system in which use standards for related agricultural chemicals are revised when residue standards are revised. Japan will conduct these activities, including the revision of the related laws.

(2) Existing food additives

(Concept)

By the 1995 Food Sanitation Law revision, the Ministry expanded the designation system, applied only to chemically synthesized food additives, to include natural food additives. As an interim measure for such revision, the Minister published a list containing natural food additives (as existing food additives) that had already been used at the time of the revision in order to continue to permit the use of them. After the law is revised, the Ministry may prohibit the use of these existing food additives, if they are found to have a problem with safety or if they are no longer in use.

(Contents of revision)

Provisions to delist food additives from the existing food additives list will be prepared. (Related to the supplementary provisions of the 1995 revised law)

(3) Securing the safety of newly developed foods

(a) Interim prohibition on the distribution of foods ingested through special fashion

(Concept)

Along with recent technical advances in the manufacturing of foods and the diversification of food imports, food whose fashion for consumption is significantly different from conventional ones, including dietary health foods, and food that contains substances that have not conventionally been provided as a food have been distributed. Since some of such foods have caused health damage, the safety of such foods should be reinforced to prevent the occurrence and expansion of harm in relation to food sanitation.

(Reference) Food Sanitation Law (1947 Law No. 233)

Article 4-2: When substances that have not been in general provided as a food and whose safety for human health has not been corroborated, or materials that contain such substances, are or will be newly sold as a food, the Minister of Health, Labour and Welfare can prohibit the sale of such materials for use as food after consultation with the Pharmaceutical Affairs and Food Sanitation Council if it is recognized that the prohibition is necessary for the prevention of the occurrence of harm in relation to food sanitation.

(Contents of the revision)

The same measures as those stipulated in Article 4-2 of the present Food Sanitation Law can be implemented with regard to food similar to that in the following and food whose safety for human health has not been corroborated. (Related to Article 4-2)

- (i) Food whose fashion for consumption is significantly different from conventional ones, such as in a concentrated form
- (ii) Food that may contain substances that have not been in general provided as a food and have caused health damage to people who have consumed them
- (b) Prohibition of false and/or exaggerated claims related to health benefits in advertising

(Concept)

The provision of appropriate information to consumers should be introduced through appropriate advertising related to health foods and other foods. This is aimed at the prevention of cases where consumers, who depend upon such health foods whose effect has not been verified, may forgo the opportunity to consult a doctor, for example.

(Contents of the revision)

Advertising that makes false and/or exaggerated claims related to health benefits from the ingestion of food will be prohibited. (Related to the Health Promotion Law)

3. Inspection and laboratory test systems

- (1) Improving inspection and laboratory test systems

(Concept)

In response to the increase in the importation of foods, the diversification of imported food, and more complex distribution modes in domestic markets, inspection and laboratory test systems should be improved through various approaches, including the utilization of private corporations.

(Contents of the revision)

(a) Abolition of the Cabinet Ordinance designation of foods subject to laboratory test

The requirement for the Cabinet Ordinance designation of foods subject to laboratory test under "inspection order" will be abolished to allow for flexibility in responses to violations of the law according to the likelihood of such violations. (When the foods that are subject to the "inspection order" fail to pass the ordered test, the importation and distribution of these foods may not be approved. (Related to Article 15)

(b) Registered laboratories

At present, the category of laboratories that implement laboratory tests under "inspection order" is limited to public corporations designated by the Minister of Health, Labour and Welfare. However, this system will be changed, and private corporations will be able to be registered as the laboratories if they meet the requirements for equity, neutrality and capabilities on laboratory tests that are of the same order as the presently designated laboratories. (Related to Chapter 5-2)

(c) Entrustment of monitoring tests to registered laboratories

Monitoring tests, which the quarantine stations currently conduct the sampling and examination of imported food, will be able to be entrusted to the registered laboratories described in (b) above. (Related to Articles 17 and 19-2)

(d) Formulation and publication of guidelines for inspection and guidance as well as a plan for implementing the inspection and laboratory test of imported food.

The Minister of Health, Labour and Welfare will formulate and publicize guidelines that provide to prefectures the important points of inspection and guidance as well as a plan for implementing the inspection and laboratory tests of imported food.. (Newly provided)

(e) Introduction of prefectural plans for inspection and guidance related to food sanitation

At present, the Cabinet Ordinance stipulates that food sanitation inspectors should check sanitary conditions and provide guidance at frequencies set according to the types of facilities. This system will be changed to a new one in which each prefecture formulates a plan for inspection and guidance in accordance with the local circumstances and publicizes this, in consideration of (d) above. (Related to Article 19)

(2) Urging businesses to make greater efforts to secure food safety

(a) Review of the HACCP approval system

(Concept)

There have been some cases in which foods have caused significant food poisoning even though the foods had been produced by the concerned businesses that have incorporated the HACCP (Hazard Analysis Critical Control Point) system, a self-regulation system adopted by businesses to secure food safety, and have been approved by the government. This approval system, therefore, should be reviewed so that businesses will regularly improve their conditions themselves.

(Contents of the revision)

A renewal system will be introduced into the HACCP approval system under the jurisdiction of the Minister of Health, Labour and Welfare. (Related to Article 7-3)

(b) Added responsibilities of food sanitation administrators

(Concept)

Food sanitation administrators, who assume responsibilities regarding sanitation in relation to the manufacturing and processing operations of foods that require special sanitary considerations, will assume new responsibilities in relation to self-regulation and the observance of laws and regulations.

(Contents of the revision)

Food sanitation administrators will have to offer their views as required to ensure the observance of laws and regulations by businesses. Meanwhile, businesses will have to respect these views. (Related to Article 19-17)

4. Reinforcement of the responses to foodborne incidents such as food poisoning

(1) Directions by the Minister of Health, Labour and Welfare when large-scale food poisoning incidents have occurred over a wide area

(Concept)

In recent years, the coverage of food distribution systems has broadened, and, accordingly, the incidence of food poisoning caused by the same food has occurred over a wider area than previously. In response to this trend, cases of food poisoning or other harmful incidents should be quickly dealt with through government direction to prevent further harm.

(Contents of the revision)

The Minister of Health, Labour and Welfare will be able to direct the governors of prefectures to conduct the necessary investigations when it is recognized that such direction is required for the prevention of the occurrence or expansion of harm caused by foods. The governors, on their part, will have to report the results of the directed investigations to the Minister of Health, Labour and Welfare. (Newly provided)

(2) Investigations and reports by the directors of health centers

(Concept)

The present Food Sanitation Law stipulates that the directors of health centers will conduct investigations when medical doctors notify them of cases of food poisoning. However, the directors should be able to promptly implement measures without the required notification from doctors.

(Contents of the revision)

It will be provided that the directors of health centers can conduct investigations without notifications from medical doctors in order to identify the cause of incidents such as food poisoning. At the same time, provisions related to reports to the government will be prepared. (Related to Article 27)

(3) New provision concerning the obligation of dealers to strive to maintain records

(Concept)

When cases of food poisoning have occurred, the records related to the suppliers of the raw materials or the products, etc. need to be referred to in order to identify the cause and prevent extension of the damage.

(Contents of the revision)

Dealers in foods will have to strive to maintain records related to the suppliers, etc. (Newly provided)

5. Strengthening of penalties (including those for the violation of labeling obligations)

(Concept)

Penalties for violation of the Food Sanitation Law should be reviewed in order to prompt businesses into self-observance of the law.

(Contents of the revision)

The required review will be conducted, including an increase in fines for the violation of labeling obligations and an increase in fines imposed on corporations. (Related to Chapter 9)

IV. Other

The government will enforce necessary revisions of the laws prescribing food sanitation regulations, such as the Abattoir Law.

END MHLW TENTATIVE TRANSLATION